



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM21/0429

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DES MOINES IA 50309-2721

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/739,264	10/29/96	014	ZEMAN, M	1643 04/29/98
First Named Applicant	MARSHALL, WILLIAM E.			

TITLE OF INVENTION METHODS AND COMPOSITIONS FOR MODULATING IMMUNE SYSTEMS OF ANIMALS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	424-282.100	D56	UTILITY	YES	\$660.00	07/29/98

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

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- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
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**III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.**

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

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Box ISSUE FEE  
Assistant Commissioner for Patents  
Washington, D.C. 20231

**MAILING INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE. Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

ZARLEY MCKEE THOMTE  
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## Certificate of Mailing

I hereby certify that this Issue Fee Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above on the date indicated below.

Barbara Sease (Depositor's name)

Barbara Sease (Signature)

7-22-98 (Date)

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/739,264	10/29/96	014	ZEMAN, M	1643 04/29/98
First Named Applicant	MARSHALL, WILLIAM E.			

TITLE OF INVENTION METHODS AND COMPOSITIONS FOR MODULATING IMMUNE SYSTEMS OF ANIMALS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	424-282.100	D56	UTILITY	YES	\$660.00	07/29/98

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47) attached.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 ZARLEY, MCKEE, THOMTE, VOORHEES & SEASE  
801 Grand Ave., Suite 3200  
2 DES MOINES, IOWA 50309-2721

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)  
**PLEASE NOTE:** Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE IMMUNOM TECHNOLOGIES, INC.

(B) RESIDENCE: (CITY & STATE OR COUNTRY) BEDFORD HILLS, NEW YORK

Please check the appropriate assignee category indicated below (will not be printed on the patent)

☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fees are enclosed (make check payable to Commissioner of Patents and Trademarks):

☒ Issue Fee

☐ Advance Order - # of Copies \_\_\_\_\_

4b. The following fees or deficiency in these fees should be charged to:

DEPOSIT ACCOUNT NUMBER 26-0084  
(ENCLOSE AN EXTRA COPY OF THIS FORM)

☐ Issue Fee

☐ Advance Order - # of Copies \_\_\_\_\_

The COMMISSIONER OF PATENTS AND TRADEMARKS IS requested to apply the Issue Fee to the application identified above.

(Authorized Signature)

(Date)

7-22-98

NOTE: The Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

**Burden Hour Statement:** This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND FEES AND THIS FORM TO: Box Issue Fee, Assistant Commissioner for Patents, Washington D.C. 20231

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TRANSMIT THIS FORM WITH FEE

# Notice of Allowability

Application No.

08/739,264

Applicant(s)

Marshall et al.

Examiner

Mary K Zeman

Group Art Unit

1815



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to the amendment and declarations filed 1/20/98 and 4/23/98.

☒ The allowed claim(s) is/are 1, 3, 4, 7, 24-26, and 28-34.

☐ The drawings filed on \_\_\_\_\_ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☒ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☐ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☐ including change required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. \_\_\_\_\_.

☐ including changes required by the proposed drawing correction filed on \_\_\_\_\_, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Notice of Informal Patent Application, PTO-152

☒ Interview Summary, PTO-413

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

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Art Unit: 1643

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Heidi Nebel on 4/23/98.

2. The application has been amended as follows:

Claims 2, 6 and 27 have been canceled.

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Claim 1. A method for activating and modulating the immune system of an animal comprising:

(a) growing bacteria in a medium, wherein the bacteria is of a class selected from the group consisting of *Lactobacillus*, *Staphylococcus*, *Streptococcus*, *Pseudomonas*, *Bacillus*, *Escherichia*, *Enterococcus*, and *Klebsiella*;

(b) exposing said bacteria to biological, chemical or physical stress so that the bacteria release a stress release product into the medium;

(c) removing said bacteria from said medium and said stress release product to form a separated product;

(d) filtering said separated product through a filter having a 10,000 dalton molecular weight cutoff to obtain said stress release product; and

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Art Unit: 1643

B1  
cont'd

(e) administering an effective amount of said stress release product to said animal.

[ In claim 3, line 1, "said step" has been replaced with "the step"

Claim ~~24~~<sup>5</sup>. A method for modulating the immune system of an animal comprising:

administering to said animal an effective amount of a product released by bacteria in response to stress wherein the stress release product is made by a method comprising:

(a) growing bacteria in a medium, wherein the bacteria is of a class selected from the group consisting of *Lactobacillus*, *Staphylococcus*, *Streptococcus*, *Pseudomonas*,

*Bacillus*, *Escherichia*, *Enterococcus*, and *Klebsiella*;

(b) exposing said bacteria to biological, chemical or physical stress so that the bacteria release a stress release product into the medium;

(c) removing said bacteria from said medium and said stress release product to form a separated product;

(d) filtering said separated product through a filter having a 10,000 dalton molecular weight cutoff to obtain said stress release product; and

(e) administering an effective amount of said stress release product to said animal.

and further providing that the stress release product is administered to the animal in a delivery form selected from the group consisting of forms for parenteral delivery, gels for oral delivery, lozenges for oral delivery, nasal sprays, ear drops, vaginal creams, vaginal suppositories, and topical ointments.

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Art Unit: 1643

Claim 26: "the product" has been replaced with "said stress release product" and "stress factors" has been replaced with "said stress release product"

Claim 28: "the product" has been replaced with "said stress release product"

Claim 29: "factors have" has been replaced with "product has"

Claim 30: "the product" has been replaced with "said stress release product"

Claim 31: "the product" has been replaced with "said stress release product" and "to produce higher levels.....pathogen" has been deleted.

<sup>12</sup>  
Claim 32: A method of maintaining the viability of bacteria during storage and shipment comprising:

administering to said bacteria a product released by bacteria in response to stress, wherein the stress release product is made by a method comprising:

b7  
(a) growing bacteria in a medium, wherein the bacteria is of a class selected from the group consisting of *Lactobacillus*, *Staphylococcus*, *Streptococcus*, *Pseudomonas*, *Bacillus*, *Escherichia*, *Enterococcus*, and *Klebsiella*;

(b) exposing said bacteria to biological, chemical or physical stress so that the bacteria release a stress release product into the medium;

(c) removing said bacteria from said medium and said stress release product to form a separated product; and

(d) filtering said separated product through a filter having a 10,000 dalton molecular weight cutoff to obtain said stress release product.

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Art Unit: 1643

Claim 33: "pneurmoniae" has been replaced with "pneumoniae"

Claim <sup>14</sup>34: A method for activating and modulating the immune system of an animal comprising:

(a) growing bacteria in a medium, wherein the bacteria is selected from the group consisting of *L. acidophilus*, *L. caseii*, *L. fermentum*, *L. plantarum*, *L. monocytogenes*, *S. aureus*, *S.*

*typhimurium*, *P. acidolactici*, *B. coryneforme*, *E. coli*, *E. faecium*, *S. pyogenes*, and *K.*

*pneumoniae*;

BK (b) exposing said bacteria to biological, chemical or physical stress such that the bacteria release a stress release product;

(c) removing said bacteria from said medium and said stress release product to form a separated product;

(d) filtering said separated product through a filter having a 10,000 dalton molecular weight cutoff to obtain said stress release product; and

(e) administering an effective amount of said stress release product to said animal.

3. The following is an examiner's statement of reasons for allowance: The claimed invention is drawn to methods of modulating the immune system of an animal by providing a factor released by bacteria under various stressed conditions. The factor, as yet, has not been characterized, but is identified by way of its molecular weight, absorption, and activity. Applicant has provided evidence that the factors of the invention are not bacteriocins, another factor produced by bacteria. Applicant has also provided a 132 declaration disclosing many additional stresses under which the claimed factors are produced. The factors produced by all of these methods are said to

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Art Unit: 1643

modulate the immune system. The art of record does not teach or suggest that products released by stress would have the effects shown on the immune system.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 8:00 am and 5:30 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz  
April 23, 1998

  
MARIAN C. KNODE  
SUPERVISORY PATENT EXAMINER  
GROUP 1800 / 602

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